



The way forward for the New Approach

KEY MESSAGES

In a competitive global environment, it is of great importance that the EU provides a legislative framework allowing for innovation and rapid response to changes in the marketplace and business models. In order to do so, regulation should be implemented in ways that draws on expertise from industry experts and users. The New Approach to technical harmonisation allows for such flexibility and stakeholder inclusion. It worked well over the last decades and is worth maintaining for the future.

- 1** Harmonised European standards (hENs) are essentially a consensus by stakeholders on how to both meet market needs and comply appropriately with regulation. Balance should be restored between the role hENs play to meet market needs in developing state-of-the-art technical solutions, and their role to support compliance with harmonised EU regulations.
- 2** In view of existing problems with the functioning of the New Approach to technical harmonisation a fundamental discussion on standardisation and the role of industry is necessary. Industry is and should remain a key actor in this process. Not only do they provide the necessary technical know-how, but also manufacturers are the main end-users of hENs when they implement the standards in their products.
- 3** The problems with the functioning of the New Approach are the result of a contested interpretation of EU Regulation 1025/2012 following recent case law of the European Court of Justice. In order to safeguard continued industry participation in the standardisation process, it is necessary to ensure both a swift publication of the reference to the hENs in the Official Journal, and sufficient flexibility in the Commission standardisation request to ensure market relevance.

Evolution of the New Approach

The New Approach is essentially a framework dealing with Single Market harmonisation for products. At present, there are several problems with the functioning of the New Approach to technical harmonisation, which will be outlined in this section. For a short background and context of the New Approach to technical harmonisation, please see the annex to this paper.



The New Approach has worked well in many product areas such as machinery, toys and electronic consumer products, where it has helped to improve EU competitiveness and enhance innovation. Under the New Approach, Union harmonisation is limited to essential requirements that are of public interest, which are obligations to obtain a result without specifying the technical solutions.¹ The Low Voltage Directive for example foresees adequate protection “against the danger of physical injury or other harm”, which is further elaborated in a wide range of harmonised European standards (hENs) which are used by manufacturers of, amongst others, electric household appliances.

Compared to the “old approach”, the New Approach has been faster, more flexible and more responsive to market needs. Recently however the functioning of the New Approach has been jeopardised. Rather than being industry-driven, the process of drafting harmonised standards has become increasingly bureaucratic and politicized, both in terms of planning and implementation.

As a result, it has become less attractive for companies to engage in the drafting and using of harmonised standards, which will inevitably reduce regulatory homogeneity in the Single Market because manufacturers are not only disincentivised to participate in the drafting of the harmonised standards, but will also move to alternative methods to demonstrate compliance.² It is key to ensure participation of industry in the standardisation process both because of their knowledge of the market and technologies, and because use of the hENs is voluntary. Therefore, if manufacturers do not find that hENs add value, they will not be taken up in practice.

Industry has repeatedly raised concerns on the increased influence of the European Commission on the European standardisation process - both in drafting the standardisation request and before the citation of harmonised standards in the Official Journal. This influence is most notably reflected in a Commission verification document on the publication of references³ and increasingly detailed standardisation requests rather than framework mandates.⁴ In a recent Communication, the Commission has announced further guidance on this ‘new format’ of standardisation requests.⁵

The Commission holds that these are obligations imposed by the Court in the *James Eliot* and *Global Garden* cases.⁶ However, these developments deepen the existing backlog in publication of hENs and narrow the ability of market parties to seek the best solution to legal and market needs within the scope of the mandate for the hEN. Addressing market needs is an important function of standards: it is even the *only* function of all non-harmonised standards. If the market relevance of a hEN declines, the

¹ Blue Guide, p. 39: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726\(02\)&from=BG](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG)

² See also: <http://www.orgalime.org/sites/default/files/position-papers/Orgalime%20Position%20Paper%20-%20Save%20the%20New%20Approach%20-%2007-03-2017.pdf>

³ Document from 16 November 2016: https://portal.etsi.org/Portals/0/TBpages/edithelp/Docs/OJEU_CITATION_EC_CHECKLIST.pdf

⁴ The first of these ‘new style mandates’ was personal protective equipment.

⁵ Communication on Harmonised Standards, 22.11.2018, p.5 <https://ec.europa.eu/docsroom/documents/32615>

⁶ Case C-613/14 of 27 October 2016 and Case T-474/15 of January 2017.



incentives for industry to contribute to the making of the standard will decline as well, and so will the uptake of the standard. European standardisation organisations CEN and CENELEC have indicated that they cannot support assumptions resulting from the interpretation of the recent case-law where these are incompatible with the voluntary nature of standards.⁷

To keep the EU competitive in a global environment, it is key that regulation is responsive to new technological developments and implemented in ways that draws in expertise from industry experts and users. Legislation should therefore contain common objectives with margins of freedom for stakeholders on how to best achieve these objectives. The New Approach to technical harmonisation allows for such flexibility and stakeholder inclusion. It worked well over the last decades and is worth maintaining for the future, especially given the fast-changing environment in the evolution of digitalisation.

The way forward

While some solutions have been put forward to resolve the problems highlighted in this paper, in our view these do not address the fundamental concerns with the functioning of the system. The Commission aimed at modernising the European Standardisation System through the 'Joint initiative on Standardisation' (JIS). In our view, the JIS has worked well as an additional mechanism to identify and discuss problems in the system with a broad range of stakeholders but has not worked properly as a tool to solve these problems. While we appreciate the action plan to reduce the backlog in the citation of hENs and the Commission's commitments to this extent announced in the recent Communication,⁸ this is no structural solution for the critical impacts caused by the increasingly prescriptive nature of the Commission's intervention in the process.

The interpretation of EU Regulation 1025/2012 by the Commission services and the European Court has become highly problematic for the functioning of the New Approach. **BusinessEurope recommends restoring a way of working that respects standards as market driven tools that can complement legislation and support compliance management.** In the view of BusinessEurope, the following issues should be solved in order to ensure industry participation in the standardisation process and hence to ensure uptake of the hENs in practice:

- **Harmonised European standards should be put back in the hands of self-regulating stakeholders**, with public authorities at EU and national level in a guiding and guarding role rather than the driving seat, as it was initially foreseen when establishing the New Approach. A clear outline of the responsibilities and tasks of the different actors in the process of drafting harmonised standards is necessary.

⁷ CEN and CENELEC's response to the Communication of the European Commission on harmonised standards of 22 November (published 18 December 2018): https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/CEN-CENELEC-Response-to-EC-COM-764.pdf

⁸ Action plan of 9 October 2017: <http://ec.europa.eu/docsroom/documents/25881>; Commission Communication on harmonised standards, 22 November 2018: <https://ec.europa.eu/docsroom/documents/32615>



- **It is key that the framework nature of the essential requirements is maintained**, leaving flexibility for as to how to achieve the ends. There should be no bureaucratic interference with planning and execution of standardisation work, and excessive setting of requirements for standards that are incompatible with the nature of standardisation and harvesting the societal benefits.
- **The backlog in the citation of harmonised European standards in the Official Journal should be eliminated**, and a swift citation modus should be guaranteed in the future, which will allow their use for the presumption of compliance by industry.

BusinessEurope therefore finds it necessary to resolutely and unambiguously reaffirm the principles of the New Approach in order to eliminate present obstacles that hinge on differences of legal interpretation. Industry welcomes a path of open and solution-based dialogue with the Commission and recommends a reassessment of the interpretations of the case-law in line with the principle of proportionality and keeping in mind the necessary industry incentives to contribute to the drafting of hENs. When the Commission and stakeholders are unable to solve the above issues on the interpretation of EU Regulation 1025/12 in a satisfactory manner, it should be considered to revise the Regulation itself.



ANNEX: What is the New Approach to technical harmonisation?

The framework for the 'New Approach to technical harmonisation' was set out in 1985 by [Council Resolution](#). Consecutively, EU [Regulation 765/2008](#)⁹ and [Decision 768/2008](#) established the New Legislative Framework bringing together the elements related to compliance of industrial products (accreditation and market surveillance). EU [Regulation 1025/2012](#) concerns European harmonised standards and currently provides the main legal framework for operation of the New Approach, while the 'Blue Guide' ([Commission Notice, last updated in 2016](#)) gives further guidance on the implementation of the system. Sectors that fall under the New Approach include but are not limited to toys, electronic consumer products and machinery.

Harmonised European standards (hENs) play a key role in the New Approach. hENs are not only a voluntary consensus on how to meet market needs, as is the case for non-harmonised European standards, global standards and national standards, but are in addition also a tool for industry to better comply with EU regulation and facilitate the free movement of goods in the Single Market. hENs are used to lay down the technical specifications of essential requirements ensuring the adequate protection of consumers, public health and the environment or other aspects of public interest protection from EU legislation.

Main steps in the process of drafting a hEN include the following. In a first step, EU legislation lays down essential (preferably performance or functional) requirements. In a second step, the European Commission drafts a request for a hEN. In a third step, the hEN is drafted by the European Standardisation Organisations (ESOs): CEN, CENELEC or ETSI. Working groups in these ESOs are comprised of industry and other relevant stakeholder experts who draft the standard on a voluntary basis. In the case of a non-harmonised European standard, the standardisation work of the ESOs is initiated by stakeholder initiative rather than a Commission request. In a fourth step, the Commission publishes a reference to the hEN in the Official Journal.

Companies are the users of the hENs: once the reference is published in the Official Journal, they can use the hEN as a compliance tool. Products manufactured in compliance with the hEN enjoy a presumption of conformity with the essential requirements from the EU legislation. It is not mandatory to use the hENs.¹⁰ To indicate compliance (either through hENs or through other means), companies apply the CE (Conformité Européenne) - marking to their product.

It is key that the responsibility for compliance, i.e. the liability remains with the manufacturer. A product manufactured in compliance with the hEN can still be demonstrated to not obey the legal requirements in case there is such evidence. There are also mechanisms in place to suspend the publication of a standard and revise it in case the presumption of conformity flowing from its application appears to be unjustified, as currently set out in Article 11 of EU Regulation 1025/2012. Therefore, the presumption of conformity does not pose any risk of negligence to public authorities.

⁹ As potentially amended by the proposal for a new Regulation on Compliance and Enforcement of 19 December 2017 (part of the "Goods package").

¹⁰ See also EP IMCO report of 9 June 2017 under 4:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2017-0213+0+DOC+XML+V0//EN&language=en>